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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118

7590 06/09/2009

BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204

EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,962	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-22,25-29 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-22,25-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the amendment filed 4/15/2009. Claims 1, 5-7, 12, 22, and 25-29 have been amended, claims 4, 23, 24, 30, and 31 have been cancelled, and no claims have been added. Thus, claims 1, 3, 5-22, 25-29, and 32 are currently pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (US 4,340,046) in view of Stuart (US 5,778,877).

Regarding claims 1, 3, 6, Cox discloses a tracheostomy tube comprising a hollow tubular body (12) having a proximal and a distal end portion and a curved portion intermediate the proximate and distal end portions (see Figure 3; both in use the tube curves and the coagulations themselves can be considered a curved portion); and a flange (16) situated at said proximal end portion and extending radially therefrom (see Figure 1), said flange being capable of selective attachment to said tubular body and removal therefrom by a snap-fit (column 5, lines 4-11). Cox is silent as to a collar with a groove for mating with a cut-away portion (38) on the flange. However, Stuart discloses, in a similar trach tube device, a collar (12) with a groove (15) for cooperatively engaging a flange (11) cut-away portion (26) extending radially inward from a

lateral side of the flange. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the tube of Cox with a collar including a groove to mate with a flange cut-away portion as taught by Stuart in order to allow the flange to pivot as needed on the patient's neck as taught by Stuart. Whether the collar is integral with the hollow tubular body or not is considered an obvious design consideration to one of ordinary skill in the art because both integral and removable collars are well known and commonly used in the art and making something integral or separable does not patentably distinguish over the prior art absent a critical teaching and/or showing of unexpected results.

Regarding claims 5 and 7, the cam portion (22) or rib (28) can be considered a barb or snap provided for attaching the collar to the flange via a receptacle (narrow part 34 of 14). Whether the cut-away portion or groove/receptacle is located on the collar or flange is an obvious design consideration to one of ordinary skill in the art involving a mere rearrangement of parts that does not patentably distinguish over the prior art absent a critical teaching and/or showing of unexpected results. Furthermore, it appears that the modified device would perform equally well the groove being located on either the collar or the flange portion so long as the two were able to mate in a locking position to allow swiveling.

Regarding claim 9, Cox discloses an inflatable cuff (14) surrounding a part of the distal end portion and an inflation line (54) connecting the cuff to a source of inflation fluid.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Mizus (US 4,960,122).

Regarding claims 12-14, Cox discloses an insertion device comprising a trach tube (10) and a loading dilator (18), the trach tube having a longitudinal bore and a tapered distal tip (see Figure 2); the loading dilator having a larger-diameter stepped proximal portion (near reference character 70 in Figure 2) and a smaller diameter distal portion (68) extending from said larger diameter proximal portion, said smaller diameter portion having a generally cylindrical profile and a tapered distal end (72), the smaller diameter portion being sized to be insertable through the longitudinal bore of said trach tube such that the tapered distal end extends axially beyond the tapered distal tip of the trach tube (see Figure 3), the trach tube further comprising a stop portion/larger-diameter collar (64) at said proximal end for engaging a distal portion of the larger-diameter stepped portion of the dilator to limit axially movement of the dilator through the trach tube (see Figure 3). Note that the term "portion" has no definite structural limitation and can include sections of varying diameter and as interpreted by examiner the smaller diameter portion includes tip 72 and tube 68, both of which have a smaller diameter than the smallest diameter of the stepped portion 70.

The difference between the instant claims and Cox is that Cox lacks the cylindrical profile tapering to the tapered distal end. However, Mizus discloses a tracheostomy tube (column 2, line 65) with a loading dilator having a cylindrical profile that tapers to a tapered distal tip (see Figure 5) that extends beyond the end of the tube (see Figure 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the loading dilator of Cox to have a cylindrical profile that tapers to a tapered distal tip as taught by Mizus because such shape is well known in the art for facilitating the insertion of trach tubes

and a mere change in shape without a change in function does not patentably distinguish over the prior art.

Regarding claims 15 and 16, as seen in Figure 3 of Cox, the tapered end of the trach tube and the dilator are complementary such that a generally smooth conical insertion tip is defined thereby and has a profile sufficient for dilating an opening in the body of a patient for inserting of said trach tube. In addition, depending on how far the tapered dilator of Mizus was inserted a generally smooth conical tip would be defined and it would have been obvious to have a smooth conical insertion tip as taught by Cox because it would have allowed a smooth transition from dilator to tube for more comfortable insertion.

Regarding claim 17, Cox teaches the stepped proximal portion of the dilator comprises a gripping surface (i.e., user grasps the end of the portion 70 to remove the dilator).

Regarding claims 18-20, Cox is silent as to the material of the insertion device or the device being molded integrally. However, absent a critical teaching and/or a showing of unexpected results from making the gripping surface from one of the claimed polymers or integrally molding the dilator components, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the dilator from a thermoplastic polymer and/or to have integrally molded the dilator components because such materials and processes are well known and commonly used in the art for easily making trach tubes and their associated components comfortable, durable, and biocompatible. Furthermore, it appears as though the modified device of Cox would perform equally well if made of a thermoplastic polymer or integrally molded.

Regarding claim 21, Cox does not specifically disclose that the stepped portion includes a longitudinal passageway that receives a portion of the smaller diameter portion. However, absent a critical teaching and/or a showing of unexpected results from securing the smaller diameter portion in a longitudinal bore of the stepped portion, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have secured the smaller diameter portion in a longitudinal bore of the stepped portion because it would have provided a well known and commonly used means for permanently securing the pieces together (i.e., either interference fit or with an adhesive in the bore for example) in such a way that the pieces would not become separated during removal of the dilator.

Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Varner (US 6,105,577).

Regarding claim 22, Cox discloses a device for percutaneous insertion into the trachea comprising a trach tube having a longitudinal passageway there through, said trach tube having a proximal end exterior to the trachea and a distal end portion insertable into the trachea, said trach tube further having and a flange (16) situated at said proximal end portion and extending radially therefrom (see Figure 1), said flange being capable of selective attachment to said tubular body and removal therefrom by a snap-fit after the distal end portion has been inserted into the trachea (column 5, lines 4-11); and a dilator (18) for inserting into the longitudinal passageway for dilating an opening in said trachea.

Cox is silent as to a locking assembly for locking the trach tube to the dilator during insertion of said trach tube. However, Varner discloses an inner cannula including locking means

(130) for securing the tube to the trach tube which includes a securement member (130) engageable with a complementary member (117) on the trach tube. The collar/cap bottom surface of the locking assembly is considered a stop member disposed on an outer surface of the dilator to prevent excess axial movement of the dilator into the trach tube (as is also disclosed by Cox and collar 64 stopping movement via handle 70). The stop member is engageable with the securement member and complementary member of the locking assembly and is prevented from sliding along the dilator when axial force is applied by virtue of the tight fit (especially if only a small amount of axial force is applied). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have including the locking means taught by Varner in the dilator of Cox in order to secure the dilator to the trach tube during insertion so that the tapered distal tip didn't accidentally slip axially up into the trach tube or for keeping the two pieces secured as a unit until needed for removal. Furthermore, it appears as though the device of Cox would perform equally well with a locking means as taught by Varner because the locking means still allows removal of the cannula/dilator as needed. In addition, Varner does not specifically disclose that the collar is permanently attached or that it slides along the tube, but it would have been obvious to have permanently secured the stop member/collar to the tube such that the components fit together without having excess tube extending beyond the collar (i.e., to prevent movement with even larger axial forces).

Regarding claims 25-26, the collar of Varner is a fitted annular ring. As discussed above, even though Varner is silent as to the collar being permanently secured to the tube, examiner contends that is would have been obvious to one of ordinary skill in the art to permanently attach

the collar to the tube (i.e., via adhesive for example), thus making the stop member integral with the dilator.

Regarding claims 27 and 28, the complementary member of Varner includes a collar on the trach tube (see Figure 4). Whether the collar is integral with or fitted on the tube is considered an obvious design consideration to one of ordinary skill in the art because integral collars and fitted exterior collars are both well known and commonly used in the art for permanently securing collars to trach tubes. Furthermore, it appears as though the locking assembly of Varner as used in Cox would perform equally well if the collar were either integral or fitted exteriorly.

Regarding claim 29, Varner discloses slot securement members not screw threads. However, absent a critical teaching and/or showing of unexpected results from using threads examiner contends that teeth/slots and threads are well known equivalents for removably securing two pieces together and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the teeth/slots with threads because threads would have provided a well known and commonly used means for removably securing the two tubes together. Furthermore, it appears as though the locking assembly of Varner would have performed equally well with threads as opposed to teeth/slots.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Stuart as applied to claims 1, 3, 5-7 and 9 above, and further in view of Varner (US 6,105,577). Cox is silent as to inserting a removable inner cannula into the tubular body. However, Varner discloses, in a similar trach tube, a removable inner cannula (128). Therefore,

it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cox's device with a removable inner cannula as taught by Varner to use as a liner that can be removed and cleaned for the more permanent trach tube.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Stuart as applied to claims 1, 3, 5-7 and 9 above, and further in view of Collins (US 6,799,574). Cox discloses the inflation line as threaded through loops but is silent as to the line being peelable. However, Collins discloses a peelable inflation line that allows the inflation line to be kept neatly with the tube shaft along most of the length (column 3, lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Cox to include a peelable inflation line as taught by Collins in order to keep the inflation line neatly with the tube shaft. Furthermore, it appears as though the device of Cox would perform equally well with a peelable inflation line.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Mizus as applied to claims 12-21 above, and further in view of Lester (US 5,928,198). Cox is silent as to a central lumen extending substantially through the loading dilator. However, Lester discloses a loading dilator (2) having a central lumen (25) extending substantially there through. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cox's dilator with a central lumen as taught by Lester in order to allow the patient to breath while the device is being inserted.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox, Stuart and Collins as applied to claim 10 above, and further in view of Rutter (US 7,140,369). Cox as modified by Collins is silent as to trimming the tubular body to a trim line and the inflation line being peelable to a point below the trim line. However, Rutter discloses that trimming the proximal end of a trach tube is well known in the art for accommodating various sizes of patients such as pediatrics and adults (column 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have trimmed the tube of Cox as modified by Collins to a location above where the inflation line can be peeled for accommodating patients of varying sizes as taught by Rutter.

Response to Arguments

Applicant's arguments regarding the Cox reference alone have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 4/15/2009 have been fully considered but they are not persuasive.

In response to applicant's argument that Stuart does not teach a flange which may be attached by "simply sliding" the flange onto the tube, examiner contends that these arguments are not commensurate with the scope of the claims because all that is required is a flange that can be removably attached to the tube, which is clearly taught by Cox, and a cut-away portion/groove, which is clearly taught by Stuart. The term "cut-away portion" doesn't limit the portion in the broadest reasonable interpretation to that seen in the figures of the instant invention (limitations from the specification are not read into the claims), but merely only an

arbitrary portion of the flange that has been "cut-away" in some manner and that extends inwardly from a lateral side of the flange. As discussed above, motivation for combining the two references lies in the teaching of Stuart that the cut-away portion/groove allows swiveling of the flange to accommodate movement of a wearer.

In response to applicant's argument that inner cannulas cannot be equated to loading dilators, examiner respectfully disagrees and points to the cited prior art for support. Both inner cannulas and loading dilators are inserted into the central bore of the trach tube and allowing the two tubes to be properly secured adds stability and ensures that no inadvertent separation occurs until desired. Whether the inner tube was for dilating or just for a lining is not relevant to the desire or capability of locking the tubes together. Thus, one of ordinary skill in the art would in fact find motivation for using taught features of a locking mechanism on an inner cannula for an inner loading dilator as discussed above. Additionally, examiner notes that the same problem addressed by the applicant does not need to be explicitly taught in the prior art for a combination to be proper, as long as motivation is found implicitly or explicitly in the reference (as is here as discussed above). The locking mechanism of Varner on the dilator of Cox would in fact allow the same problem (i.e., pulling the trach tube back by pulling on the dilator) to be solved as the instant invention albeit the combination was made for a different initial motivation. Furthermore, examiner notes that applicant argues the gripping teeth are a different structure from the instant invention. However, again examiner points out the limitations from the specification are not read into the claim, and all that is claimed is a "securement member," a "complimentary member," and "stop member, " none of which provide any definite structural limitations that distinguish over the locking mechanism of Varner as discussed above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cohen is cited as showing a trach tube in which both a loading dilator and inner cannula can be locked to the trach tube.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771